

PATENT Attorney Docket No. INL-054DV (4643/107)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Dahlbäck et al.

SERIAL NO .:

10/037,296

GROUP NO.:

1644

FILING DATE:

EXAMINER: December 21, 2001

Not yet assigned.

TITLE:

METHODS AND REAGENTS FOR DETERMINING PROTEIN S

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any documents referred to as enclosed herein, are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, Washington, DC 20231 on this 10th day of December, 2002.

Commissioner for Patents Washington, D.C. 20231

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Sir:

Submitted herewith are:

- 1. Transmittal Form (1 page);
- 2. Information Disclosure Statement (2 pages);
- 3. Form PTO-1449 (13 pages);
- 4. References Labeled A1 A44, B1 B16 and C1-C156; and
- 5. A return receipt postcard.

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	Check Attached	_	Parts of Applic	cation (PTO-1553)		of Patent Appeals ar	d Interferences
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\boxtimes	Information Disclosure Statement ✓ Form PTO-1449		Small Entity S	tatement	i		
	(13 pgs.) Copies of IDS Citations (A1-A44, B1-B16 and C1-C156)		CD(s) for large program	e table or computer			
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Direct	Testa, Hu High Stre 125 High Boston, N Tel. No.:	et Tower	hibeault, LLP) -7000	Date: December 10 Reg. No. 43,153 Tel. No.: (617) 310 Fax No.: (617) 248	-8168	Diana M. Steel Attorney for the App Testa, Hurwitz & TH High Street Tower 125 High Street Boston MA 02110	plicants nibeault, LLP



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Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed:

\boxtimes	(1)	within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. 1.114; or
	(2)	after the period defined in (1) but before the mailing date of a final action or a notice of allowance under 37 C.F.R. 1.311, and
		the requisite Statement is below, OR
		the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or

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]	(3)	after the mailing date of a final action or notice of allowance but before the payment of the issue fee, AND
		the requisite Statement is below, AND
		the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that:

- 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R.

 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Date: December 10, 2002

Reg. No. 43,153

Tel. No.: (617) 310-8168 Fax No.: (617) 248-7100 Diana M. Steel

Attorney for Applicants

Testa, Hurwitz, & Thibeault, LLP

High Street Tower 125 High Street

Boston, Massachusetts 02110



EXAMPTO – 1449

INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: INL-054DV

APPLICANTS: Dahlbäck et al.

SERIAL NO.: 10/037,296

FILING DATE: December 21, 2001

GROUP: 1644

U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1 4,622,389		11/11/86	Nagasawa et al.	530	331	05/09/85
	A2	4,692,406	09/08/87	Becker et al.	435	13	08/20/84
	A3	4,755,461	07/05/88	Lawson et al.	435	13	04/17/86
	A4	4,849,403	07/18/89	Stocker et al.	514	2	05/09/86
	A5	5,001,069	03/19/91	Bartl et al.	436	86	10/04/88
-	A6	5,051,357	09/24/91	Hassouna	435	13	08/21/89
	A7	5,059,525	10/22/91	Bartl et al.	435	13	05/29/90
	A8	5,147,805	09/15/92	Preda et al.	436	86	06/29/90
-	A9	5,169,786	12/08/92	Carroll et al.	436	69	12/19/89
	A10	5,187,067	02/16/93	Koike et al.	435	7.9	03/14/91
	A11	5,200,322	04/06/93	Matsumoto	435	13	02/28/91
<u> </u>	A12	5,223,427	06/29/93	Edgington et al.	435	240.27	03/09/88
	A13	5,254,350	10/19/93	Barrow et al.	424	570	07/22/91
	A14	5,270,451	12/14/93	Hawkins et al.	530	381	08/06/92
	A15	5,308,756	05/03/94	van de Waart et al.	435	13	11/20/91
	A16	5,314,695	05/24/94	Brown	424	450	10/29/91
***	A17	5,358,853	10/25/94	Butler et al.	435	13	08/03/92
<u>.</u>	A18	5,374,617	12/20/94	Morrissey et al.	514	8	05/13/92
	A19	5,391,380	02/21/95	Barrow et al.	424	570	05/14/93
	A20	5,405,946	04/11/95	Griffin et al.	530	380	12/02/92
_	A21	5,418,141	05/23/95	Zweig et al.	435	13	05/06/94
	A22	5,426,031	06/20/95	Hawkins et al.	435	13	05/25/93
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	A24	5,443,960	08/22/95	Dahlbäck	435	13	05/27/94
	A25	5,472,850	12/05/95	Morrissey	435	13	04/10/91

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EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A26	5,502,651	03/26/96	Jackson et al.	364	509	05/02/94
	A27	5,504,064	04/02/96	Morrissey et al.	514	8	02/19/93
	A28	5,504,067	04/02/96	Morrissey et al.	514	8	10/12/94
	A29	5,506,112	04/09/96	Lang et al.	435	13	01/10/92
	A30	5,508,170	04/16/96	Butler et al.	435	13	06/03/94
	A31	5,525,478	06/11/96	Matschiner	435	13	06/07/95
	A32	5,597,700	01/28/97	Konstantinov et al.	435	7.92	04/28/94
	A33	5,643,739	07/01/97	Varadi et al.	435	13	05/01/95
	A34	5,705,395	01/06/98	Griffin et al.	436	69	11/14/94
	A35	5,716,795	02/10/98	Matschiner	435	13	01/03/96
	A36	5,726,028	03/10/98	Kraus	435	13	08/04/95
	A37	5,753,510	05/19/98	Kraus	436	16	11/07/95
	A38	5,766,869	06/16/98	Arkel et al.	435	13	11/27/96
	A39	5,780,255	07/14/98	Preda	435	23	06/09/95
	A40	5,834,223	11/10/98	Griffin et al.	435	13	12/18/97
	A41	5,858,724	01/12/99	Novy, Jr. et al.	435	69.6	07/16/96
	A42	5,874,256	02/23/99	Bertina et al.	435	69.6	02/21/97
	A43	6,083,757	07/04/00	Griffin et al.	436	69	11/10/98
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EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	BI	0 229 234 A1	07/22/87	EP			10/16/86	English	No
	B2	0 271 810 A2	06/22/88	ЕР			12/08/87	No	Yes

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	B3	0 286 323 B1	12/15/93	EP			03/31/88	No	Yes	ĺ
	B4	0 434 377 B1	08/23/95	EP			12/18/90	No	Yes	1
	B5	88/07543	10/06/88	PCT			03/29/88	No.	Yes	1
	B6	90/11368	10/04/90	PCT			03/19/90	No	Yes	
	B7	91/01382	02/07/91	PCT			07/04/90	No	Yes	
	B8	91/01383	02/07/91	PCT			07/5/90	No	Yes	
	B9	91/02812	03/07/91	PCT			08/06/90	No	Yes	
 .	B10	92/08479	05/29/92	PCT			11/04/91	No	Yes	
	B11	93/01209	01/21/93	PCT			07/02/92	No	Yes	
	B12	93/07492	04/15/93	PCT			09/25/92	No	Yes	
	B13	93/10261	05/27/93	PCT			05/13/92	No	Yes	
		93/13211	07/08/93	PCT			12/29/92	No	Yes	
	B15	93/23074	11/25/93	PCT			05/12/93	No	Yes	
	B16	95/21938	08/17/95	PCT			02/14/95	No	Yes	
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NIT.	ОТН	ER DOCUMENT	S: (Includii	ng Author, Titl	e, Date, R	elevant Pa	ges, Place of	Publication)		
	Cl	Amer et al. "Impairment of the Protein C Anticoagulant Pathway in a Patient with Systemic Lupus Erythematosus, Anticardiolipin Antibodies and Thrombosis," Thrombosis Research, 57:247-258 (1990).								
	C2	Amiral et al. "New Direct Assay of Free Protein S Antigen Using Two Distinct Monoclonal Antibodies Specific for the Free Form," Blood Coag. Fibrin., 5:179-186 (1994).								
	C3 "Antigen-Antibody Crossed Electrophoresis," Analytical Biochemi							58-361 (1965).		
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	C5	Bader et al. "Mu and Synthetic Pho	lticentric Eva ospholipids,"	aluation of a Ne Thromb. Haem	w PT Reag	gent Based :292-299 (on Recombin	ant Human Tissi	le Factor	
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INFORMATION DISCLOSURE STATEMENT

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	GROUP: 1644			
	OTHER ART, JOURNAL ARTICLES, ETC.			
C6	Baele et al. "Comparison of a Recombinant Thromboplastin with Thrombotest™ for Oral Anticoagulant Control," <u>Haemost.</u> , 26:11-15 (1996).			
C7	Bauer "Hypercoaguability-A New Cofactor in the Protein C Anticoagulant Pathway," New England Journal of Medicine, 330:566-567 (1994).			
C8	Beauchamp et al. "High Prevalence of a Mutation in the Factor V Gene Within the U.K. Population: Relationship to Activated Protein C Resistance and Familial Thrombosis," <u>British J. of Haemost.</u> , 88:219-222 (1994).			
C9	Beck et al. "Protein C: ein Inhibitor der Blutgerinnung," <u>Diagnose & Labor</u> , 38:35-42 (Abstract in English) (1988).			
C10	Bertina "Specificity of Protein C and Protein S Assays," Res. Clin. Lab., 20:127-138 (1990).			
C11	Bertina et al. "Mutation in Blood Coagulation Factor V Associated with Resistance to Activated Protein C," Nature, 369:64-67 (1994).			
C12	Bertina et al. "Determination of Plasma Protein S – The Protein Cofactor of Activated Protein C," Thrombosis Haemostasis, 53:268-272 (1985).			
C13	Blangero et al. "Normal Activated Protein C Response has a Large Genetic Component," Florencia, PS-920 p. 226 (6/9/97).			
C14	Blangero et al. "Genetic Factors Influence Quantitative Variation in Tissue Factor Pathway Inhibitor," Florencia, PS-1666, p. 409 (1997).			
C15	Blombäck <i>et al.</i> "Chromogenic Peptide Substrates in the Laboratory Diagnosis of Clotting Disorders," <u>Haemostasis and Thrombosis</u> , Bloom and Thomas (eds.), 2 nd ed, 967-981 (1987).			
C16	Boyer-Neumann <i>et al.</i> "Comparison of Functional Assays for Protein S: European Collaborative Study of Patients with Congenital and Acquired Deficiency," <u>Thomb. and Haemost.</u> , 70(6):946-950 (1993).			
C17	Chromogenix, Coatest APC Resistance Kit instructions, May 1993.			
C18	Chromogenix, Coatest APC Resistance Kit Brochure, June 1993.			
C19	Comp "Laboratory Evaluation of Protein S Status," <u>Seminars in Thromb. and Haemost.</u> , 16(2):177-181 (1990).			
C20	Comp et al. "An Abnormal Plasma Distribution of Protein S Occurs in Functional Protein S Deficiency" Blood, 67(2):504-508 (1986).			
C21	Cornillon et al. "Rat Coagulation Factor V Purification and Production of the Monospecific Antiserum," Comp. Biochem. Physiol., 83B, 2: 397-401 (1986).			
C22	"Correlation of the APC Ratio with Free Protein S Antigen and with Protein C Activity" Appendix 5, 3 pages (Publication date not known).			
C23	Cripe et al. "Structure of the Gene for Human Coagulation Factor V," Biochemistry, 31: 3777-3785 (1992).			
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	OTHER ART, JOURNAL ARTICLES, ETC.				
C2	Dahlbäck "Protein S and C4b-Binding Protein: Components Involved in the Regulation of the Protein C Anticoagulant System" Thromb. Haemost., 66(1):49-61 (1991).				
C2	Dahlbäck et al. "Primary Structure of Bovine Vitamin K-Dependent Protein S" Proc. Natl. Acad. Sci., 83:4199-4203 (1986).				
C20	Dahlbäck et al. "Characterization of Functionally Important Domains in Human Vitamin K-Dependent Protein S Using Monoclonal Antibodies" J. Biol. Chem., 265(14):8127-8135 (1990).				
C2*	Dahlbäck, <i>et al.</i> "The Protein C Anticoagulant System" <u>The Molecular Basis of Blood Disease</u> , W.B. Saunders Company, Philadelphia, PA, 599-627 (1994).				
C28	Dahlbäck et al. "Resistance to Activated Protein C, the FV:Q ⁵⁰⁶ Allele, and Venous Thrombosis," Ann. Hematol., 72:166-176 (1996).				
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C30	Dahlbäck "Factor V Gene Mutation Causing Inherited Resistance to Activated Protein C as a Basis for Venous Thromboembolism," J. Intern. Med., 237:221-227 (1995).				
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C32	Dahlbäck "A New Model for Coagulation Factor V Suggesting a Unique Mechanism of Activation," <u>Scand.</u> <u>J. Clin. Lab. Invest.</u> , 48, Suppl. 191:47-61 (1988).				
C33	Dahlbäck "Factor VIII Defect Associated with Familial Thrombophilia," Thrombosis & Haemostatis, 65, Abstract 39:658 (1991).				
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C35	Dahlbäck "Thrombophilia: The Discovery of Activated Protein C Resistance," <u>Advances in Genetics:</u> <u>Incorporating Molecular Genetic Medicine</u> , Academic Press, (Hall <i>et al.</i> eds.), 135-175 (1995).				
C36	Dahlbäck <i>et al.</i> "A Natural Anticoagulant Pathway: Proteins C, S, C4b-Binding Protein an Thrombomodulin," <u>Haemostasis and Thrombosis</u> (Bloom <i>et al.</i> eds.), 3 rd edition, Churchill Livingstone, 671-698 (1994).				
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C38	D'Angelo "7 Prothrombin Time Standardization: The Problem of the Control Plasma," <u>Eur. J. Clin. Chem.</u> <u>Clin. Biochem.</u> , 33(12):1019-1022 (1995).				
C39	Denson et al. "Validity of the INR System for Patients with Liver Impairment," Thromb. Haemost., 73(1):162 (1995).				
C40	Deutsche Norm, DIN 58 911 "Kalibrierung ven Gerinnugngszeit-MeBverfahren," 3 pages (English translation provided) (1988).				
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STATEMENT

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	OTHER ART, JOURNAL	L ARTICLES, ETC.	1901
C41	Deutsche Norm DIN 58 939 "Refererzplasma,"		
C42	Diagnostika Stago "STACLOT® PROTEIN CA	Additional Information," 1 page (Publication date unknown	1).
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C49	Esmon "Protein C: Biochemistry, Physiology, an	and Clinical Implications," <u>Blood</u> , 62:1155-1158 (1983).	
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C51	Faioni et al. "Low Levels of the Anticoagulant A Insufficiency: an Inhibitor of Protein C is Present 66(4):420-425 (1991).	Activity of Protein C in Patients with Chronic Renal nt in Uremic Plasma," <u>Thrombosis and Haemostasis</u> ,	
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C53	Faioni et al. "Resistance to Activated Protein C ir Functional Assay," <u>Thromb. and Haemost.</u> , 70(6):	in Nine Thrombophilic Families: Interference in a Protein S):1067-1071 (1993).	_
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C56	Folsom <i>et al.</i> "Prospective Study of Hemostatic Fa Circulation, 96(4):1102-1108 (1997).	Factors and Incidence of Coronary Heart Disease,"	1
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 	OTHER ART, JOURNAL ARTICLES, ETC.
C58	Garí et al. "The Influence of Low Protein S Plasma Levels in Young Women, on the Definition of Normal Range," Thromb. Res., 73(2):149-152 (1994).
C59	Giddings et al. "Chapter 12: Laboratory Support in the Diagnosis of Coagulation Disorders," Clinics in Haematology," 14(2):571-595 (1985).
C60	Griffin et al. "Anticoagulant Protein C Pathway Defective in Majority of Thrombophilic Patients," <u>Blood</u> , 82(7):1989-1993 (1993).
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